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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,615	06/13/2001	Michael W. Johnson	S63.2-9949	7299

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EXAMINER

COZART, JERMIE E

ART UNIT PAPER NUMBER

3726

DATE MAILED: 01/08/2004

16

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/880,615

Applicant(s)

JOHNSON, MICHAEL W.

Examiner

Jermie Cozart

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 23-41 is/are pending in the application.
- 4a) Of the above claim(s) 31 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-30 and 32-40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 23, 25, 26, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yan (5,843,172) in view of Solovay (5,769,884).

Yan discloses a method of manufacturing a stent comprising providing a tube having at least two different longitudinally spaced regions of different predetermined physical characteristics (different pore sizes located along the stent), and subsequently cutting the stent from the tube. Yan also discloses the step of disposing a treatment agent on the stent. The cutting step includes forming a plurality of openings (52) which are elongate. The cutting step also includes forming a plurality of openings (68) whose widths exceed their lengths. See *column 2, lines 7-14; column 6, lines 61-column 7, line 7; column 7, lines 30-52; and Figures 2, 6, and 8 for further clarification.*

Yan, however, does not disclose the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference, or a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, being characterized by a second porosity different from the first porosity.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 6) and each region having substantially the same porosity about its circumference, wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity. *See column 3, line 41 – column 6, line 55, and Figures 2, 6, 6A, and 6D for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide the tube of Yan with at least two different longitudinally spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, and wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity, in light of the teachings of Solovay, in order to effectively deliver different amounts of medication to a particular site within the human body.

3. Claims 23-30 and 32-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richter in view of Solovay (5,769,884) and Saunders (5,780,807).

Richter discloses a stent (1) having at least two longitudinally spaced regions (8, 9) and (8', 9') of different predetermined physical characteristics. A first portion (8, 9) of the tube is made from a first metal and a second portion (8', 9') of the tube, longitudinally spaced from the first portion is made from a second metal different from the first metal.

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Richter discloses a plurality of serpentine bands or segments (Fig. 11) extending about the circumference of the stent, and at least some of the openings being bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment. Richter discloses openings (Fig. 11) which are bounded at a proximal end by a first serpentine segment and at a distal end by a second serpentine segment including a first side wall (Fig. 11) and a second side wall (Fig. 11) extending between and connecting the first and second serpentine segments. The first and the second side walls (Fig. 11) are non-parallel to the longitudinal axis of the stent. The first and second serpentine segments having different physical characteristics. Richter discloses at least some of the openings being bounded at a proximal end by a first serpentine segment made of a first metal and at a distal end by a second serpentine segment made of a second metal different from the first metal. See column 1, lines 36-54; column 1, line 66 – column 2, line 2; column 4, lines 32 – 40; column 6, lines 5-7, lines 42 – 51, and lines 57-60; column 7, line 63 – column 8, line 22; and Figures 1, 2, and 7-11 for further clarification.

Richter, however, does not disclose the following: the tube having at least two different longitudinally spaced regions of different predetermined porosities and each region having substantially the same porosity about its circumference; a first portion of the tube being characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube being characterized by a second porosity different from the first porosity; disposing a treatment agent on the stent; a first band having a different porosity than a second band; subsequently cutting the stent from a tube; the cutting step including forming a plurality of serpentine segments which

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extend about the circumference of the stent; the cutting step including forming a plurality of openings which are elongate; the cutting step including forming a plurality of openings whose widths exceed their length; or cutting a plurality of openings in the tube to form a stent.

Solovay discloses a stent covering (30) which is formed into a tube around the stent wherein the tube has at least two different longitudinally spaced regions (12, 13) of different predetermined porosities (see Fig. 5 and 6) wherein each region has substantially the same porosity about its circumference, and wherein a first portion (12) of the tube is characterized by a first porosity and second portion (13) of the tube, longitudinally spaced from the first portion of the tube, is characterized by a second porosity different from the first porosity. Solovay also discloses disposing a treatment agent (col. 6, lines 47-55) on the stent via of the stent covering. Solovay as shown in Figures 5A-5E discloses first and second fibers or bands with different porosities. See *column 3, line 41 – column 6, line 55, and Figures 2 and 5A-6E for further clarification.*

Saunders'807 discloses cutting a stent (10) from a tube (21), wherein the cutting step including forming a plurality of serpentine segments (30) which extend about the circumference of the stent, forming a plurality of openings (not labeled) which are elongate and whose widths exceed their length, and cutting a plurality of openings in the tube (21) to form a stent (10). See *column 6, line 64 - column 7, line 22, and Figures 4-6 for further clarification.*

Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention the provide tube of Richter with at least two different longitudinally

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spaced regions of different predetermined porosities wherein each region has substantially the same porosity about its circumference, wherein a first portion of the tube is characterized by a first porosity and second portion of the tube, longitudinally spaced from the first portion of the tube is characterized by a second porosity different from the first porosity, to dispose a treatment agent on the stent of Richter, to provide the tube of Richter with a first band having a different porosity than a second band, to cut the stent of Richter from a tube, wherein the cutting step includes forming the plurality of serpentine segments which extend about the circumference of the stent, to form the plurality of openings which are elongate and whose widths exceed their length, and to cut the plurality of openings in the tube to form the stent, in light of the teachings of Solovay and Saunders'807, in order to effectively deliver different amounts of medication to a particular site within the human body and to provide a precision cut stent enabling greater precision reliability, structural integrity and overall quality without burrs or other imperfections.

### ***Response to Arguments***

4. Applicant's arguments, see pages 4-6, filed 10/24/03, with respect to the rejection(s) of claim(s) 23, 25, 26, 29, 30, 32, 34, and 35 under 35 USC 102(e) as being clearly anticipated by Yan, the rejection of claims 23, 24, 27-30, 32, 33, and 36-40 under 35 USC 103(a) as being unpatentable over Richter in view of Saunders, and the rejection of claims 27, 28, and 36-39 under 35 USC 103(a) as being unpatentable over Yan in view of Gray et al. have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new

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ground(s) of rejection is made in view of the combination of Yan and Solovay, and the combination of Richter, Solovay and Saunders.

***Conclusion***

5. Telephone inquiries regarding the status of applications or other general questions, by persons entitled to the information, should be directed to the group clerical personnel. In as much as the official records and applications are located in the clerical section of the examining groups, the clerical personnel can readily provide status information. M.P.E.P. 203.08. The Group clerical receptionist number is (703) 308-1148.

6. If in receiving this Office Action it is apparent to applicant that certain documents are missing, e.g., copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers or other general questions should be directed to Tech Center 3700 Customer Service at (703) 306-5648, or fax (703) 872-9301 or by email to [CustomerService3700@uspto.gov](mailto:CustomerService3700@uspto.gov).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jermie Cozart whose telephone number is 703-305-0126. The examiner can normally be reached on Monday-Thursday, 7:30 am - 6:00 pm.

8. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 703-308-1789. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

Listed below are a few helpful numbers and web address for The United States Patent and Trademark Office.

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Information Help Line	(800) 786-9199
Internet PTO-Home Page	<a href="http://www.uspto.gov">http:// www.uspto.gov</a>

*Jerome E. Coyne*

JC *K*  
January 6, 2004